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10/596,389	02/05/2007	David M. Hampson	82047001/P3138-US	5991
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Intellectual Property Dept. Dewitt Ross & Stevens SC 2 East Mifflin Street Suite 600 Madison, WI 53703-2865			YOUNG, RACHEL T	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/596,389	Applicant(s) HAMPSON ET AL.
	Examiner RACHEL T. YOUNG	Art Unit 3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on **24 November 2009**.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) **11-29** is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) **11-29** is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Amendment

1. This office action is responsive to the amendment filed on 11/24/09. As directed by the amendment: claims 11-13 have been amended, claims 1-10 have been canceled, and new claims 19-29 have been added. Thus, claims 11-29 are presently pending in the application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 11-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11, lines 7-8 recites "extending **at least about** their peripheral edges". It is unclear what applicant means by this indefinite language. Claim 13, line 4, claim 16, line 4 and claim 19, line 12 recites that the bladder "is not affixed to the inner sheet of the device", however this is unclear because during use the bladder will be affixed to the inner sheet of the device.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 25-29 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 25 recites part of the human body in combination with the device, e.g. lines 6-7 recite "fastened together about the circumference of a limb with the inflatable bladder being situated along the circumference of the limb", which is suggested to be changed to **-adapted to be fastened together about the circumference of a limb with the inflatable bladder being adapted to be situated along the circumference of the limb--**. It has been held that a claim directed to or including within its scope, a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of limited, but exclusive property right in a human being is prohibited by the constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970). For examination purposes, all claims will be considered as if such limitations involving the combination with a human were not present.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 19-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Grosso (2003/0125650).

Regarding claim 19, in figure 9 Grosso discloses an inflatable compression device including flexible inner (inner sheet of pocket B) and outer sheets (outer sheet of pocket A) having adjacent facing surfaces, with the facing surface of each sheet defining at least a major portion of the sheet's area, and peripheral edges bounding the facing surfaces (the inner and outer sheets create enclosed pouches A and B as can be seen in the picture, and therefore must be bound at the peripheries), and the inner and outer sheets are joined at least at the peripheral edges, with the inner and outer sheets extending across a noninflatable area (52 and 20 define the mesh and straps noninflatable area) the facing surfaces of the inner and outer sheets are adjacently situated, an inflatable area (16, Fig. 3, Page 4, ¶ 38) adjacent the noninflatable area, the inflatable area including an inflatable bladder 16 between the inner and outer sheets, with the bladder being affixed to the outer sheet (16 is inserted into pocket A against the outer sheet, and when worn and fully inflated is then affixed to the outer sheet), and not being affixed to the inner sheet (16 is not affixed to the inner sheet because it is separated by the dividing mesh that separate pockets A and B).

Regarding claim 20, Grosso discloses that at least a substantial portion of the inner sheet defines a heating element (the heating element is disposed within pocket B and therefore would heat the entire inner sheet, Page 4, ¶ 38).

Regarding claim 21, Grosso discloses that the heating element includes conductive material (the heating element is a hot pack and thus must contain conductive material in order to get hot, Page 4, ¶ 38).

Regarding claim 22, in Fig. 9 Grosso discloses that the noninflatable area includes a flap 20 having a fastener thereon (there are fasteners at the ends of the noninflatable portion 20 in Fig. 9 and can be best seen in Fig. 1 as 14, Page 3, ¶ 31).

Regarding claim 23, in Fig. 9 Grosso discloses that the noninflatable area bears fasteners (can also be seen in Fig. 1 as 14) thereon, and the fasteners of the noninflatable area can be joined (Page 3, ¶ 31) and the compression device is defined by a closed loop bearing the inflatable area and the joined noninflatable areas.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grosso.

Regarding claim 25, in Fig. 9 Grosso discloses an inflatable compression device including an at least substantially planar flexible body (inner and outer sheet of 52 are flexible, Page 4, para 38 "rubber"), the body including an inflatable bladder 16, and noninflatable portions (20, 52) located at least on opposite sides of the inflatable bladder, the noninflatable portions bearing fasteners (14, Page 3, para 31) and the noninflatable portions may be fastened together about the circumference of a user's back (Page 1, para 9) with the inflatable bladder being situated along the circumference of the back (Page 1, para 9), the body being formed of joined inner and outer sheets (inner and outer of sheets of pockets B and A) with the bladder being situated therebetween (16 is inserted into pocket B, between the inner and outer sheets), with the inner sheet not being joined to the bladder (16 does not come in contact with the inner sheet B due to the folded structure of mesh 52 that separates pockets A and B), and including a heating element (Page 4, para 38). Although Grosso discloses that the device is made to go around the waist of a user, rather than a limb, it would have been obvious to place the device around a limb such as the thigh of a user in need of compression therapy because Grosso discloses an adjustment member (38 Fig. 1, Page 3, para 31) and it appears that the device would perform equally well around the limb of a user as compared to the back.

Regarding claim 26, Grosso discloses that the bladder is joined to the outer sheet (bladder 16 is placed in outer pocket A and when inflated and worn, 16 would be joined with the outer sheet).

Regarding claims 27-28, Grosso discloses a heating element disposed on the inner sheet (Page 4, para 38) and that the heating element includes a conductive material (the hot pack must include a conductive material in order to get hot), however Grosso lacks detail regarding that the heating element extends across at least a major portion of the inner sheet and the entirety of the inner sheet. Grosso, however, does disclose that pockets A and B should be large enough to contain a hot pack (Page 4, para 38), which indicates that the size of the inner sheet and the hot pack are of similar size and that the hot pack extends across at least a major portion of the inner sheet and across the entire inner sheet. Since Grosso contemplates the size of the inner sheet with regards to the hot pack it would have been obvious to one of ordinary skill in the art to adjust the size of the inner pocket to accommodate the size of the hot pack, as disclosed by Grosso, for the purpose of providing therapy to a sufficient area of the user.

11. Claims 11-15, 24 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grosso (2003/0125650) in view of Kuiper et al. (2003/0191420).

Regarding claim 11, 24 and 29, in fig. 1-3 Grosso discloses an inflatable compression device with an outer sheet 21, an inner sheet 20 extending at least substantially parallel to the outer sheet, an inflatable bladder (16, Page 3, ¶ 33) situated between the inner and outer sheets, and the inner and outer sheet include adjacent

facing surfaces bounded by peripheral edges (the inner and outer sheet create a enclosed pouch for 16 as can be seen in the picture, and therefore must be bound at the peripheries), the facing surfaces having joined areas extending at least about their peripheral edges, with the facing surfaces being separated adjacent the joined areas (Fig. 3 shows that the inner and outer layer are separated to allow for bladder 16), an inflatable bladder 16 is situated between the inner and outer sheets, with the bladder being situated on the facing surface of the outer sheet (when the device is worn by the user the bladder is then situated on the outer sheet), the facing surface of the inner sheet being spaced away from the interior of the inflatable bladder (Fig. 3), and the joined areas being situated about the inflatable bladder. Grosso is silent regarding the outer layer being an inextensible material, however Kuiper teaches an inelastic outer layer 22 of a compression device (Fig. 4, Page 5, ¶ 66). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Grosso's outer sheet with an inextensible material, as taught by Kuiper, to keep the shape of the compression device when inflating (Page 5, ¶ 66).

Regarding claim 12, in figs. 1-3 Grosso discloses that the bladder is spaced from at least a portion of the joined peripheries areas.

Regarding claims 13 and 16, Grosso discloses that the bladder is affixed to the outer sheet of the device (when the bladder is inflated enough or worn by the user), and not affixed to the inner sheet of the device (when the device is not inflated as much or deflated).

Regarding claim 14, Grosso discloses an inner sheet, but is silent regarding heating elements within the inner sheet, however Grosso discloses another embodiment in Fig. 9 in which a mesh material 52 is folded and stitched to create pockets A and B in which the cushion and a hot pack can be inserted (Page 4, ¶ 138). Grosso discloses that a hot pack can be inserted into pocket B, on the inner side of the belt in contact with the inner sheet. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Grosso's inner sheet with a heating element, as disclosed by Grosso, for the purpose of providing therapy to the user.

Regarding claim 15, the modified Grosso discloses that the entirety of the inner sheet is heated (the hot pack is in direct contact with the inner sheet so it would inherently heat the entire inner sheet).

12. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grosso/Kiuper as applied to claim 11 above, and further in view of Arkans (6,007,559).

Regarding claim 17, in Fig. 1 Grosso discloses a pump 32 in communication with a bladder 16, but is silent regarding that the pump cyclically provides gas to the bladder and that the pump repeatedly provides gas to the bladder for up to 2/10 of a minute and subsequently removing gas from the bladder for the remainder of the minute. However, Arkan's teaches a cyclical pump for providing gas to a bladder for about 3 seconds (Col. 11, ll. 25-28) and removing gas from the bladder (Col. 11, ll. 25-28) and gas from the bladder for the up to a minute (Col. 11, ll. 25-28). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify

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Grosso's pump with a cyclical pump to provide a specific inflation and inflation cycle, as taught by Arkans, for the purpose of providing an appropriate therapy for a patient (Col. 11, ll. 18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide gas for 2/10 of a minute, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art, and it appears that the modified Grosso device would perform equally as well with an extended inflation period. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claim 18, the modified Grosso pump of claim 17 is silent regarding that it provides a pressure of no greater than approximately 60 mmHg. However, Arkans teaches providing a pressure of 45 mmHg. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Grosso's pump pressure to no greater than approximately 60 mmHg, as taught by Arkans, for the purpose of providing the appropriate therapy for the patient. Although Arkans teaches a range of pressure provided to the patient higher and lower than 60 mmHg, discovering an optimum value of a result effective variable involves only routine skill in the art, and it appears that providing a pressure of no greater than 60 mmHg would work effectively using Grosso's modified pump. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

13. Applicant's arguments with respect to claims 11-29 have been considered but are moot in view of the new grounds of rejection.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ben-Noon (6,010,471) to a body treatment apparatus, Kelly et al. (5,383,919) to a thermal therapy pad, and Rutt et al. (6,592,543) to an inflatable medical appliance. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL T. YOUNG whose telephone number is (571)270-1481. The examiner can normally be reached on mon-thurs 7 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RACHEL T YOUNG/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771